

Remarks

Claims 7-11, 14, 15, 21, and 23-25 are pending. Claims 7-11, 14, 15, 21, 23, and 24 stand rejected under 35 U.S.C. 103(a). Claims 7, 11, 14 and 21 have been amended and new independent claim 25 has been added.

Applicants respectfully request reconsideration and allowance of the above-identified application in view of the above amendments and following remarks.

35 USC 103(a) (Claims 7-11, 14, 15, 21, 23, 24; Dor/Mulhauser and Das):

The Examiner rejects claims 7-11, 14, 15, 21, 23, and 24 as unpatentable under 35 USC 103(a) over Dor in view of Mulhauser and Das. It is respectfully submitted that none of the pending claims in this application are obvious in view of these references. Reconsideration and reversal of the claim rejections based on Dor, Mulhauser and Das is respectfully requested in the light of the foregoing amendment and the following comments.

The Examiner states that the combination of the three references makes the claimed invention obvious. This rejection is traversed as follows.

An invention is unpatentable if the differences between it and the prior art would have been obvious at the time of the invention. As stated in MPEP § 2143, there are three requirements to establish a *prima facie* case of obviousness.

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure.

In regard to the suggestion or motivation to combine references, it has been stated:

“Therefore, an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue....To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the

references that would create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art reference for combination in the manner claimed.” *In re Rouffet*, 47 USPQ2d 1453, 1457-1458 (1998).

“The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

It is respectfully submitted that the Examiner has not demonstrated any suggestion or motivation to combine the references, nor that the modification of the cited prior art references points to the reasonable expectation of success in the present invention, which are the first and second requirements of the obviousness analysis. Even if such a combination were made, the invention as claimed in independent claims 7, 21 and 25 would not be achieved, since the references do not teach or suggest all the claim limitations.

The Examiner states that Dor discloses the claimed method with all the elements of claim 7, apart from affixing a triangular continuous ring to the sheet and sewing the ring to the inner surface of the inferior wall along the suture line. The Examiner further states that Mulhauser and Das teach cardiac reinforcement patches (Das, Figure 5a – 5f, and Mulhauser, column 4) which include a continuous outer frame/sewing, and that it would have been obvious to modify Dor’s patch to add a continuous frame to reinforce the patch. This argument is hereby respectfully traversed. Neither Das nor Mulhauser describe or suggest a sheet or patch which is sewn to the inner surface of the inferior wall of the heart, and which has an attached triangular continuous ring, nor any motivation for modifying Dor to provide a method using such a sheet, as discussed in more detail below.

Das describes a method of closing a septal defect in which an elastically deformable frame around the periphery of a sheet is collapsed for passage through a catheter and then elastically returns to predetermined shape when properly positioned to close the defect. The frame is not sewn to the adjacent tissue. Instead, the device in this reference comprises two discs which have central portions sewn together and each have a peripheral, elastically deformable frame. When the central portion is positioned in the defect and the frames are released, they spring out on opposite sides of atrial septum S (Fig. 10) to hold the device in place, as described in column 10, lines 16 to 24. There

is no sewing of either frame to the septum. One advantage of the procedure described by Das is that the device is delivered by a transcatheter procedure, avoiding the need for open heart surgery (column 11, lines 19 to 24). The reason for the frames in Das is not to reinforce a sheet or patch which is used to cover an opening which is made surgically, but to provide an elastically deformable device which can be inserted in an existing septal defect using a catheter. In contrast, Dor's method does require surgery to remove scarred tissue and then cover the resultant incision with a patch which is sewn in place. There is no motivation suggested by the completely different procedure of Das to provide an elastically deformable frame around Dor's patch, since such an addition would not remove the requirement for open heart surgery and there is no apparent advantage or expectation of improvement in Dor's method based on the teachings of Das.

It is therefore submitted that the proposed combination of Dor with Das does not meet the three criteria described above for establishing obviousness. First, there is no motivation suggested by these references to combine their teachings. Das is concerned with a completely different type of heart procedure from Dor, and the reason for the elastically deformable frames in Das' device has no relevance to the type of open heart surgery with a single sheet described by Dor. For Das' device to work properly, there must be two discs with outer collapsible frames, one on each side of the atrial septum, and Das provides no motivation for providing such a frame on a single sheet. One skilled in the field having no knowledge of the present invention would therefore not consider combining the teachings of these references.

Second, there is no expectation of success or improvement as a result of the proposed combination. As noted above, one of the advantages of the double discs with expandable frames in Das is to allow the device to be delivered by a transcatheter procedure, avoiding the need for open heart surgery. The surgical method of Dor requires open heart surgery, so the elastically deformable frames of Das would have no apparent advantage in such a method.

Finally, such a modification of Dor would not result in the invention as claimed in claim 7, 21, or new claim 25. Referring to claim 7, even if the deformable frame were added to Dor's patch, there is no suggestion in either reference of sewing such a continuous ring itself to the inner surface of the inferior wall. In Das, the ring or frame is not sewn in place. Further, neither reference suggests attaching a triangular continuous ring to a sheet or patch to leave an outer rim outwardly of the ring.

Instead, the deformable frames in Das are secured to the outer periphery of the respective discs. Finally, there is no suggestion of sewing a projecting outer rim of a patch to the inner surface outward of the continuous ring.

The method of claim 21 would also not be achieved by the proposed modification of Dor based on Das, since there is no suggestion in either reference of fixing a continuous ring, triangular or otherwise, to the sheet with an outer rim of the sheet extending outwardly from the ring, and of sewing the outer rim to the inner surface of the ventricle.

Further, the method of new claim 25 would not be achieved by the proposed modification. There is no suggestion of fixing a continuous ring of non-circular shape to a sheet such that an outer rim extends outwardly from the ring. Additionally, neither reference suggests sewing the patch to the inner surface of the ventricle with first sutures so that the central area of the patch defines a portion of the ventricle of the heart, and sewing an outer rim to the inner surface of the ventricle with second sutures outward of the first sutures. There is no such outer rim in either reference, and no suggestion of first and second sutures.

In combining Mulhauser with the first two references, the Examiner argues that Mulhauser teaches a cardiac reinforcement patch for locally constraining cardiac expansion (page 3, lines 6 to 8). It is respectfully submitted that the device described by Mulhauser is not a cardiac reinforcement patch. Instead, it is a device for repairing abdominal wall defects such as inguinal hernias (see column 1, lines 16 to 18, column 2, lines 23 to 28 and 56 to 62, Figure 2(b) and associated description). One skilled in the field would not consider hernia repair devices when seeking to improve on a patch as in Dor used to replace diseased or scarred ventricular tissue.

It is further argued that Mulhauser teaches providing an outer rim extending outwardly of the patch for sewing the ring to affected tissue, and that it would therefore be obvious to provide such an outer rim in Dor as modified by Das for sewing the patch to the affected tissue. This argument is also hereby respectfully traversed. Not only is the proposed combination not obvious, it also would not result in the invention as claimed without further, non-obvious modifications not suggested by any of the references.

First, there is no motivation suggested by the teachings of Das and Mulhauser for modifying Dor's patch to provide a triangular ring with an outer rim of the patch extending outwardly from the

ring for sewing the patch to affected tissue. As noted above, Dor's patch is sewn around its periphery only. The rings in Das are not sewn to the affected tissue but instead spring out to grip the tissue between them. The implant with an outer rim as in Figures 4(a) and 4(b) of Mulhausen is described as being particularly suitable for intraperitoneal procedures, i.e., inside the abdominal cavity, for example on the inner wall of the intestine or bowel. In other embodiments in Mulhausen which have no outer rim, the device is secured to the tissue at an outer peripheral ring, for example as illustrated in Figure 2(b). There is no motivation suggested by Mulhauser for one seeking to improve a patch for the ventricle of the heart as in Dor to select any of his devices, let alone the device with an outer rim as in Figure 4(a) rather than one of his devices with no outer rim, particularly since the device of Figure 4(a) is intended for surgery in a completely different organ from Dor.

Second, there is no expectation of success or improvement if the isolated features or embodiments of Das and Mulhauser were combined with the patch used in Dor's surgical method. Both Das and Mulhauser are concerned with completely different types of surgical procedure from that of Dor, with Das concerned with a device for closing an existing septal defect without requiring open heart surgery, and Mulhauser concerned with a patch or implant primarily designed for repairing abdominal wall defects. There is no suggestion in any of these references that Dor's surgical method would be improved by modifying his patch as proposed by the Examiner.

Finally, even if Dor's patch were modified to provide an outer frame as in Das with an outer rim as in Mulhauser, or a ring with an outer rim as in Mulhauser, the method as claimed in the independent claims as amended above would still not be achieved without further non-obvious modification. In fact, several steps of the claimed method would be lacking from such a combination.

First, the Examiner's reason for making a ring attached to Dor's patch triangular in shape is that it would have to be triangular since it would be attached to the peripheral edge of the triangular patch. It is respectfully submitted that this is inconsistent with the later argument that it would be obvious to provide an outer peripheral rim of the patch outside the ring. If an outer rim outside the ring is to be provided, the ring does not have to have the same peripheral shape as the patch, and there is no reason to select a triangular shape from all the ring shapes in Figure 5A to 5J of Das.

Thus, the proposed combination of Dor, Das and Mulhauser would not necessarily lead to selection of a triangular ring or a non-circular ring positioned inward of the outer periphery of the patch.

Second, such a combination would not result in two separate attachments between the patch and the tissue or surface. In Dor, the patch is sewn about its periphery only. In Das, there is no sewing involved. If Dor were modified based on Das, the patch would still be sewn about its periphery, or not sewn at all. In Mulhausen, the device of Figure 4 is attached to the tissue by staples 40 at its outer rim, outside ring 32, and is not attached to the tissue at any other location, as seen in Figure 4(b) and described in column 5, lines 39 to 55. As illustrated in Figure 4(b), the outer rim of the mesh layer 34 is stapled to the tissue around defect 17, “provisionally anchoring the implant until sufficient tissue ingrowth holds the prosthesis in place” (column 5, lines 48 to 50).

Thus, in all three references, there is only one location where the device or patch is secured to the tissue, specifically the outer rim or peripheral edge of the device, whether or not a ring is provided inward of the outer rim as in Mulhauser. Referring to claim 7, there is nothing in the teachings of any of these references to suggest sewing a continuous ring to the inner surface of the inferior wall of the heart AND sewing an outer rim to the inner surface outward of the ring. Referring to claim 21, the references do not teach sewing a patch to the inner surface of the ventricle AND sewing the outer rim to the inner surface of the ventricle outward of the portion of the ventricle defined by the central area of the patch. Referring to claim 25, the references do not teach sewing the ventricular patch to the inner surface of the ventricle with first sutures so that the central area of the patch defines a portion of the ventricle of the heart, and sewing the outer rim to the inner surface of the ventricle with second sutures outward of the first sutures and outward of the defined portion of the ventricle.

It is therefore respectfully submitted that claims 7, 21 and 25 are not obvious in view of the references cited by the Examiner, and reconsideration and reversal of the obviousness rejection is respectfully requested in the light of the foregoing amendment and argument.

Claims 8 to 11, 14 and 15 depend from claim 7 and are distinguished from the references for the same reasons as claim 7, and additionally because these claims define other method steps lacking from the references. As regards claims 11 and 14, the Examiner contends that the outer rim of the patch in Mulhauser is the portion of the material attached to the ring. This is inconsistent with claim

7 which defines an outer rim of the patch “outwardly of the ring”. In any case, these claims have been amended to define the outer rim outside the ring as being of constant width, which is not true in Figure 4(a) of Mulhauser, where the outer periphery is square while the ring is circular, so that the outer rim outside the ring is larger at the corners. This is Mulhauser’s deliberate intent, since the corners 38 create anchoring regions through which staples 40 are driven (column 5, lines 39 to 42), and there will be no staples or attachments outside the corner regions 38. The elements of claims 11 and 14 are therefore completely lacking from the references.

Referring to claim 15, none of the references suggests a triangular ring with an outer rim of the sheet or patch extending outwardly from the ring, and the sheet itself having a triangular outer periphery or shape. The Examiner contends that either Das or Mulhauser teach a sheet of biocompatible material in the shape of a triangle. However, these references do not teach a sheet of biocompatible material with the peripheral shape of a triangle, together with a ring in the shape of the triangle attached to the sheet inward of the peripheral rim of the sheet, as in claim 15. There are no outer rims in Das, with or without a triangular outer periphery. The only outer rim in Mulhauser has an outer periphery which is a different shape than the inner ring (specifically square and circular), and Mulhauser provides a specific reason for this difference in shape. There is nothing in any of the references to suggest the combination of a triangular ring attached to a sheet of biocompatible material with an outer rim projecting outside the sheet and having an outer periphery which is also triangular in shape.

Claims 23 and 24 depend from claim 21 and are distinguished from the references for the same reasons as stated above in connection with claim 21, and additionally for the same reasons as stated above in connection with claims 14 and 15.

Conclusion

On the basis of the above amendments and remarks, reconsideration and allowance of the application is believed to be warranted and such action is respectfully requested. Applicants respectfully submit that they do not acquiesce to any of the positions set forth in the Office Action(s). If the Examiner has any questions or comments regarding this amendment, the Examiner is respectfully urged to contact the undersigned at the number listed below.

Respectfully submitted,
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Dated: January 31, 2007

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